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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/318,870	05/26/1999	ANDREW H. SEGAL	3378/80489	2018

29933 7590 10/02/2002

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EXAMINER

DECLoux, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/02/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

manmade - human  
cytokine - GM-CSF  
cell-based - melanoma  
Opsonin =  
Opsonin = C3b  
Specific = anti-GM-CSF  
Specific = palmitate  
Ske. rec. = anti-GM-CSF rec.

**Office Action Summary**

Application No.

09/318,870

Applicant(s)

SEGAL, ANDREW H.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 15, 16 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-8, 13, 14, 17-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1644

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, Claims 1-2, 5-8, 13-14, 17-20 and 22-25 in Paper No. 23 filed 7-9-02, is acknowledged. The traversal is on the ground(s) that Group II (Claims 3 and 4) should be included with Group I. This has been found persuasive, and upon reconsideration, Groups I and II have been rejoined. Also upon reconsideration, the species requirement has been withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-12, 15-16, and 21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23, filed 7-9-02.

### *Priority*

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 13-14, 17-20 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a resolution step that reads on the preamble of the instant method claims.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8, 13-14, 17-20 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1644

*ant* The instant claims are drawn to a method of vaccinating a mammal comprising administering a cytokine-coated cell wherein said cytokine is exogenous to said cell. The instant specification discloses on page 11 that an exogenous cytokine refers to a cytokine which is introduced from or produced outside the cell. On page 106 of the instant specification, a method to make said cytokine-coated cell wherein said cytokine is exogenous to said cell is disclosed. Said method encompasses incubating a genetically engineered lipid-linked cytokine such as palmitate-linked GM-CSF with cells containing the target antigen. However, there is no disclosure as to the amount of GM-CSF or cytokine that adheres to the cell, and how much is necessary to be effective in a method of vaccinating a mammal to the targeted antigen. It is noted that the only in vivo disclosure regarding cytokine coated cells produced in this manner is prophetic.

Mahvi et al (Human Gene Therapy, 1997, May 1, 8(7):875-91) teach that GM-CSF induces macrophage-associated tumoricidal activity, and teaches that B-16 melanoma cells transfected with GM-CSF DNA, express, and secrete GM-CSF, and can be used as a vaccine to protect mice from subsequent tumor challenge, (see entire article especially page 879). Mahvi et al further teach on page 878, column 2, last paragraph, that the routine expression of transfected GM-CSF does not necessarily validate this treatment as a vaccination strategy. Mahvi et al teach further that in a murine neuroblastoma system the invitro expression of GM-CSF of 10 ng/10 million cells/24 hours is necessary to protect animals from subsequent tumor challenge.

Since the actual amount of cytokine on the recited cytokine coated cells that would be administered in the recited method has not been disclosed, nor has the local effective concentration of cytokine that would be available after administration of the recited cytokine coated cells been disclosed, nor has the concentration of any cytokine that would be effective in a vaccine against any antigen been disclosed, it would require undue experimentation for one of skill in the art to practice said method without further guidance and direction from the instant specification. In view of the quantity of experimentation, the limited working examples, the scope of the claims, the unpredictability in the art and the lack of sufficient guidance in the specification, it would require undue experimentation to practice the claimed invention.

### ***Conclusion***

8. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

Application/Control Number: 09/318,870

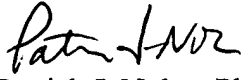
Page 4

Art Unit: 1644

organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,  
Patent Examiner,  
September 26, 2002

  
Patrick J. Nolan, Ph.D.,  
Primary Patent Examiner  
Group 1640